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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MALAMUD, DEBORAH LESLIE	
ART UNIT	**PAPER NUMBER**
3766	

DATE MAILED: 03/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/785,431	SANDERS, RICHARD S.	
	Examiner	Art Unit	
	Deborah Malamud	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-62* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32,34-44 and 46-62* is/are rejected.

7)☒ Claim(s) *33 and 45* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 February 2004 and 07 September 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/24/04, 2/14/05*, 8/25/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-6, 8-9, 11-12, 14-32, 34-44, 46-53, 55 and 58-62 are rejected under 35 U.S.C. 102(b) as being anticipated by Ideker et al (U.S. 6,205,357). Regarding claims 1-2, 8-9, 23-28 and 58, Ideker discloses (column 2, lines 16-26) a system comprising "a first sensing electrode configured for positioning through the coronary sinus ostium and within a vein on the left surface of the left ventricle of the heart for sensing electrical activity from the heart, and a detector operatively associated with the first sensing electrode for determining (e.g., diagnosing or prognosing) an arrhythmia with the sensed electrical activity. Typically the system further comprises a second sensing electrode configured for positioning in the right ventricle of the heart, where the detector is operatively associated with both the first sensing electrode and the second sensing electrode." Ideker further discloses (column 3, lines 66-67; column 4, lines 1-4) "implantable cardioverter/defibrillator (ICD) of the present invention includes an implantable housing that contains a hermetically sealed electronic circuit. The housing optionally, but preferably, includes an electrode comprising an active external portion of the housing, with the housing implanted in the left or right, preferably left, thoracic region of the patient." The examiner considers this to be a first electrode coupled to the

housing and a second electrode, and monitoring circuitry coupled to the first and second electrodes, the first and second electrodes configured for cardiac activity sensing and energy delivery when the device is operated in an energy delivery device. This monitoring circuitry also functions as detection circuitry. Ideker discloses (column 2, lines 56-65) "implantable system of the invention comprises detecting a first set of electrical activity from the heart from a first sensing electrode positioned within a vein on the surface of the left ventricle of the heart; detecting a second set of electrical activity from the heart from a second sensing electrode positioned within the right ventricle of the heart; then selecting an electrical therapy to be delivered by the implantable system based on the first and second sets of detected electrical activity; and then delivering the selected electrical therapy." The examiner considers this to teach energy delivery circuitry coupled to the first and second electrodes. The system also includes (column 3, lines 1-10) "the system includes a first catheter configured for positioning in the right ventricle of the heart; a second catheter configured for positioning through the coronary sinus ostium and in the coronary sinus of the heart, with the first and second catheters together carrying at least three defibrillation electrodes. A power supply is included, a control circuit is operatively associated with the power supply and the electrodes. The control circuit is configured to deliver atrial therapeutic pulses through at least two of the electrodes, and/or ventricular therapeutic pulses through at least two of the electrodes." The examiner considers this to be a lead interface coupled to the housing that receives a cardiac lead, and a controller coupled to the lead interface, monitoring circuitry and energy delivery circuitry. See Figures 2, 3A, 4A and 5.

Regarding claims 3 and 18, and further regarding claim 8, Ideker discloses (column 15, lines 60-65) "the pulse regimen could be altered by external input to the controller to alter for example, the waveform, the voltage, the electrode coupling, or even to retrieve data monitoring data received and stored in memory about the number of atrial fibrillation episodes and the effectiveness of the shock level." The examiner considers this to teach memory provided in the housing and coupled to the detection circuitry, the memory configured to store selected cardiac signals.

Regarding claims 4 and 14-15, Ideker discloses (column 7, lines 14-20) "electrodes shown in the positions illustrated panel 3A are, as shown in panel 3B, operatively connected to differential amplifiers (42, 42a, 42b, 42c), in turn connected to bandpass filters (44, 44a, 44b, 44c) and sensed event detector circuitry (46, 46a, 46b, 46c), contained in the ICD (40). Amplification and bandpass filtering are followed by sensed event detection." The examiner considers this to be a programmable filter coupled to the detection circuitry, the programmable filter configurable in a first filtering mode for monitoring associated with the monitoring mode and configurable in a second filtering mode for cardiac event detection associated with the energy delivery mode.

Regarding claims 5, 17, 35 and 60, and further regarding claim 58, Ideker discloses (column 11, lines 64-67; column 12, lines 1-7) "the controller, based on information from the synchronization monitor (72), typically allows or directs the preselected shock pulse to be relayed to either a discharge circuit for further processing (i.e., to further shape the waveform signal, time the pulse, etc.) or directly to a switch. The controller may also control the proper selection of the predetermined defibrillation

electrode pair(s), where multiple defibrillation electrodes are used, to direct the switch to electrically activate a desired electrode pair to align the predetermined electric shock pulse pathway through which the shock pulse is provided." The examiner considers this to teach a mode switch coupled to the controller, configured to transition the cardiac device between the monitoring mode and the energy delivery mode.

Regarding claim 6, 11-12, 36-37 and 43, and further regarding claim 58, Ideker discloses (column 15, lines 58-65) "it is also preferable that the electronic package include a receiver/transmitter coupled to the internal controller (274) for communicating with an external controller. Thus the pulse regimen could be altered by external input to the controller to alter for example, the waveform, the voltage, the electrode coupling, or even to retrieve data monitoring data received and stored in memory about the number of atrial fibrillation episodes and the effectiveness of the shock level." The examiner considers this to be a transceiver that receives a transmit request signal and transmits the contents of the memory to a patient-external device in response.

Regarding claims 16, 34, 59 and 61, Ideker discloses (column 15, lines 32-36) "pulse generator includes a single capacitor 278, and the controller 274 includes a switch (e.g., a crosspoint switch) operatively associated with that capacitor." The examiner considers this to be a hardware switch.

Regarding claims 19-22 and 29-30, Ideker discloses the presence of a lead system capable of performing each of pacing, defibrillation/cardioversion and bi-ventricular pacing therapy.

Further regarding claim 23, Ideker discloses (column 4, lines 13-16) "electrodes used to carry out the present invention are typically carried by catheters or leads, which are electrically and mechanically connected to the housing through a header unit."

Regarding claim 31, Ideker discloses (column 11, lines 40-49) "The electronic circuit (215) also includes a cardiac cycle monitor ("synchronization monitor 272") for providing synchronization information to the controller. As discussed below, the synchronization is typically provided by sensing cardiac activity in the RV, but may also include other sensing electrodes which can be combined with the defibrillation electrodes or employed separately to provide additional assurance that defibrillation shock pulses are not delivered during sensitive portions of the cardiac cycle so as to reduce the possibility of inducing ventricular fibrillation." The examiner considers this to be a lead capable of providing resynchronization pacing therapy.

Regarding claim 32, the examiner considers that processor memory inherently contains code. Providing the memory contains a mode switch feature, which Ideker's system does, that code would actuate the mode switch.

Regarding claims 38 and 41, the examiner considers Ideker to disclose a system including a device with the claimed elements, as cited in the above paragraphs.

Regarding claims 39-40 and 62, Ideker discloses (column 12, lines 8-11) "the defibrillation pulses may be triggered by an external signal administered by a physician, with the physician monitoring the patient for the appropriate time of administration." The examiner considers this to teach a trigger that is capable of being actuatable by a patient to perform the claimed functions.

Regarding claims 42, 44, 46-53 and 55, in view of the structure as disclosed by Ideker, the method of operating or using the device would be inherent because it is the normal and logical means by which the device can be used. Further regarding claim 42, Ideker discloses (column 6, lines 20-25) "The effectiveness of ICD therapy is predicated on the accurate and precise classification of cardiac rhythm. The ICD continuously monitors a patients intrinsic heart rhythm." The examiner considers this to teach loop monitoring. It is inherent in the system that the memory would store the most recent loop recording.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ideker et al (U.S. 6,205,357) in view of Funke (U.S. 4,312,355). Ideker teaches the claimed invention except for a receiver coupled to the controller, the controller switching the cardiac device between the monitoring mode and the energy delivery mode in response to the receiver receiving a switch request signal. Funke however discloses (column 3, lines 15-21) " the circuit means for detecting atrial action and/or the circuit means for detecting ventricular action comprise refractory means for blocking the detection of signals the frequency of which exceeds a predetermined maximum value.

When such high-frequency noise signals are received, the circuit means for atrial and/or ventricular detection are disabled; the pacemaker will operate at fixed frequencies." Both Ideker and Funke teach pacemakers that switch from detection to pacing modes. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Ideker's implantable system with Funke's receiver in order to quickly switch from stimulation to detection and back.

5. Claims 10, 54 and 56-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ideker et al (U.S. 6,205,357). Regarding claim 10, Ideker discloses the claimed invention but does not disclose expressly the first and second electrodes provided in or on the housing, the second electrode electrically isolated from the first electrode. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the electrode configuration as taught by Ideker, with the electrodes in or on the housing, because the applicant has not disclosed the electrodes in or on the housing provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with first electrode on the housing and the second electrode remote from the housing as taught by Ideker, because Ideker's electrodes are capable of pacing and detecting cardiac activities. Therefore, it would have been an obvious matter of design choice to modify the electrode configuration to obtain the invention as specified in the claims.

Regarding claim 54, the examiner considers it obvious that updating software would switch the mode of the system.

Regarding claims 56-57, Ideker discloses the claimed invention but does not disclose expressly the use of an epicardial lead or a subcutaneous lead. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the endocardial lead as taught by Ideker, with the epicardial or subcutaneous lead, because the applicant has not disclosed that either of these leads provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the applicant's invention to perform equally well with the lead implanted in the superior or inferior vena cava as taught by Ideker, because the leads connect the electrodes to the housing in order to pace or sense the heart. Therefore, it would have been an obvious matter of design choice to modify the lead configuration to obtain the invention as specified in the claims.

Allowable Subject Matter

6. Claims 33 and 45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Malamud whose telephone number is (571) 272-2106. The examiner can normally be reached on Monday-Friday, 8.00am-5.30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571)272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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